

Nuclear Regulatory Commission

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(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a therapeutic medical device, supervised work experience, and supervised clinical experience as follows—

(1) 200 hours of classroom and laboratory training that includes—

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity; and
- (iv) Radiation biology;

(2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes—

- (i) Review of the full calibration measurements and periodic spot-checks;
- (ii) Preparing treatment plans and calculating treatment times;
- (iii) Using administrative controls to prevent medical events;
- (iv) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical device or console; and
- (v) Checking and using survey meters; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes—

- (i) Examining individuals and reviewing their case histories to determine their suitability for teletherapy, remote afterloader, or gamma stereotactic radiosurgery treatment, and any limitations or contraindications;
- (ii) Selecting the proper dose and how it is to be administered;

(iii) Calculating the doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and

(iv) Post-administration follow up and review of case histories.

§ 35.961 Training for authorized medical physicist.

The licensee shall require the authorized medical physicist to be an individual who—

(a) Is certified by the American Board of Radiology in—

- (1) Therapeutic radiological physics;
- (2) Roentgen ray and gamma ray physics;

(3) X-ray and radium physics; or

(4) Radiological physics; or

(b) Is certified by the American Board of Medical Physics in radiation oncology physics; or

(c) Holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed 1 year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in §§ 35.67, 35.632, 35.633, 35.635, 35.642, 35.643, 35.644, 35.645 and 35.652, as applicable.

§ 35.980 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who—

(a) Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or

(b)(1) Has completed 700 hours in a structured educational program consisting of both—

(i) Didactic training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

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(E) Radiation biology; and
(ii) Supervised experience in a nuclear pharmacy involving the following—

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

[67 FR 20370, Apr. 24, 2002, as amended at 70 FR 16367, Mar. 30, 2005]

§ 35.981 Training for experienced nuclear pharmacists.

A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in § 35.980(b)(1) before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements for a preceptor statement (§ 35.980(b)(2)) and recentness of training (§ 35.59) to qualify as an authorized nuclear pharmacist.

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Subpart K—Other Medical Uses of Byproduct Material or Radiation From Byproduct Material

§ 35.1000 Other medical uses of byproduct material or radiation from byproduct material.

A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if—

(a) The applicant or licensee has submitted the information required by § 35.12(b) through (d); and

(b) The applicant or licensee has received written approval from the Commission in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Commission considers necessary for the medical use of the material.

Subpart L—Records

§ 35.2024 Records of authority and responsibilities for radiation protection programs.

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by § 35.24(e), and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by § 35.24(b), for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

§ 35.2026 Records of radiation protection program changes.

A licensee shall retain a record of each radiation protection program change made in accordance with § 35.26(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the